Serious Reportable Events in Massachusetts Hospitals: January 1, 2008 – June 30, 2008

An Interim Report

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Division of Health Care Quality

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EXECUTIVE SUMMARY

This is an interim report on patient safety data for January through June, 2008 reported to the Department of Public Health by Massachusetts hospitals pursuant to the recommendations of the commonwealth's Health Care Quality and Cost Council. During the first half of 2008, Massachusetts hospitals reported two hundred and five serious reportable events. One hundred and fifty-eight, or 77% of the total, were related to patient falls, of which six contributed to the patient's death. There were ten reports related to medication errors, ten reports of instances of a retained foreign object following surgery, and nine instances of wrong site surgery.

A. INTRODUCTION

The Department is pleased to present this first report on the status of serious event reporting by Massachusetts hospitals under the Department's new National Quality Forum-based reporting system.[1] Implemented on January 1, 2008, the system is based on the mandatory reporting by hospitals of twenty-eight (28) discrete adverse medical events grouped into six major categories: surgical, product or device related, patient protection related, care management related, environmental, and criminal.

While the Department and the Massachusetts hospital industry have a decades-long history with respect to the reporting of medical errors and investigating incidents affecting patient safety, this taxonomic or classification-based system constitutes an entirely new reporting scheme. It was developed for implementation over the course of 2007 in extensive consultation with the Board of Registration in Medicine, the Massachusetts Hospital Association and numerous other stakeholders. Initial instructions and reporting forms were distributed to all chief executive officers and risk managers of Massachusetts hospitals in early December, 2007, and further guidance and clarification circulars were sent to all affected parties throughout and beyond the initial six-month reporting period.[2] As such, we cannot over-emphasize that this is truly an "interim" report, and that the figures presented herein represent a snapshot during the system's early implementation.

While each reported incident is investigated by the Department and the respective hospital risk management personnel, lack of familiarity with the new reporting requirements and subjectivity in the interpretation of terms and criteria of reportable events by hospital staff underscore our caution about drawing any conclusions from the data during this start up period. Apart from understandable inconsistencies in

[1] National Quality Forum. *Serious Reportable Events in Healthcare-2006 Update.* Washington, D.C: National Quality Forum; 2007

[2] #07-12-478 Hospital Reporting of Serious Incidents - 12/13/2007 (PDF) and www.mass.gov/dph/dhcq

interpretation and classification, the number of reported incidents is simply too small to allow for any lessons to be derived regarding safety or quality at a particular institution at this time.

For this reason, and as recommended by the HCQCC, the data are presented in aggregate form only. We expect to produce a hospital specific report in the spring of 2009 that covers all of 2008, and when a second year of data is collected we will conduct further analyses of events sorted by race, ethnicity, age, and gender - and by other measures such as location of occurrence in hospital, time of day, protocols and procedures in place at the time of the event, and surgical specialty for example - to better serve the development of public policy and the expansion of a culture of best practices throughout the commonwealth's health care system.

B. BACKGROUND

Since the publication of the Institute of Medicine's landmark report *To Err is Human — Building a Safer Health System*[3] in 2000, and the National Quality Forum's *Serious Reportable Events in Healthcare – A Consensus Report*[4] in 2002, concerns over patient safety and medical errors have generated a wealth of public policy and fact-finding initiatives nationwide. In Massachusetts, among those initiatives was the founding of the Department's Betsey Lehman Center for Patient Safety and Medical Error Reduction[5] in 2004. Another was the enactment of Chapter 58 of the Acts of 2006 which established the Massachusetts Health Care Quality and Cost Council[6], and this summer the passage of Chapter 305 of the Acts of 2008, which empower the Council with a broad mandate to identify statewide goals for (1) improving health care quality and transparency, (2) containing health care costs, and (3) reducing racial and ethnic disparities in health care.

Consistent with this mandate, the statute requires the Department to collect such hospital-specific data on adverse medical effects and medical errors as it may require and to convey the information collected to the Betsy Lehman Center and to the Health Care Quality and Cost Council for publication. A facility failing to comply with the Department's requests for information may be fined up to $1,000 per day per violation, have its licenses revoked or suspended, or both.

In addition, the legislation directs the Department to promulgate regulations prohibiting a health care facility from charging or seeking reimbursement for services provided as a result of the occurrence of a serious reportable event. According to the legislation a health care facility may not charge or seek reimbursement for a serious reportable event that the facility has determined, through a documented review process, and under Department regulations was preventable, within its control, and

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[3] Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human – Building a Safer Health System.* Washington, DC: National Academy of Science Press; 2000

[4] National Quality Forum. *Serious Reportable Events in Healthcare: A Consensus Report.* Washington, DC: National Quality Forum; 2002

[5] mass.gov/dph/betsylehman

[6] www.mass.gov/hqcc

unambiguously the result of a system failure based on the health care provider's policies and procedures.

The objectives underlying the development of the Department's NQF-based reporting system, however, should be viewed as neither regulatory nor punitive. The most meaningful results will come from what we learn about why events happen and how they can be prevented in the future. There is little question among the stakeholders that the imposition of consistently high levels of inquiry, accountability, and transparency will foster the system-wide patient safety improvements that need to take place.

C. MDPH/NQF LISTING OF SERIOUS REPORTABLE EVENTS[7]

The Department's reporting requirements are based on the National Quality Forum's categorization of serious reportable events as follows:

1. SURGICAL EVENTS
   - A. Surgery performed on the wrong body part
   - B. Surgery performed on the wrong patient
   - C. Wrong surgical procedure performed on a patient
   - D. Unintended retention of a foreign object in a patient after surgery or other procedure
   - E. Intraoperative or immediately postoperative death in an ASA Class I patient

2. PRODUCT OR DEVICE EVENTS
   - A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
   - B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
   - C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

3. PATIENT PROTECTION EVENTS
   - A. Infant discharged to the wrong person
   - B. Patient death or serious disability associated with patient elopement (disappearance)
   - C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility

[7] National Quality Forum. *Serious Reportable Events in Healthcare-2006 Update.* Washington, D.C: National Quality Forum; 2007

4. CARE MANAGEMENT EVENTS

A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
G. Patient death or serious disability due to spinal manipulative therapy
H. Artificial insemination with the wrong donor sperm or wrong egg

5. ENVIRONMENTAL EVENTS

A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

6. CRIMINAL EVENTS

A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
B. Abduction of a patient of any age
C. Sexual assault on a patient within or on the grounds of a healthcare facility
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility

D. MASSACHUSETTS EXPERIENCE: January through June, 2008

Commencing January 1, 2008 all licensed hospitals in Massachusetts have been required to report any occurrence of a serious reportable event. For reporting purposes, in cases where hospitals have merged or otherwise combined operations (for example North Shore Medical Center – Salem and North Shore Medical Center – Union; Berkshire Medical Center – Berkshire and Berkshire Medical Center – Springfield; or Southcoast Hospitals Group, which operates three formerly independent facilities in three localities under a single license) each campus is required to report separately, consistent with similar data reporting requirements elsewhere in the Department.

The complete set of materials including reporting forms, guidelines, criteria and definitions provided by the Department to the reporting hospitals may be found on the Department's website under Hospital Circulars/Reporting Serious Incidents[8]. Hospitals were instructed to provide the following data elements on standardized forms provided for each incident of a serious reportable event. These twenty-two patient and event descriptors form the backbone of the Department's SRE reporting system.

IDENTIFICATION

- NAME - AGE; SEX; ADMISSION DATE
- AMBULATORY STATUS.
- ADL STATUS
- COGNITIVE LEVEL
- MENTALLY RETARDED/DEVELOPMENTALLY DISABLED

REPORT DETAIL

- SERIOUS REPORTABLE EVENT TEXT DESCRIPTION (from pick list)
- DPH OCCURRENCE TYPE
- TYPE OF HARM
- BODY PART AFFECTED
- PATIENT'S ACTIVITY AT TIME OF OCCURRENCE
- PLACE OF OCCURRENCE
- EQUIPMENT, IF ANY, BEING USED AT TIME OF OCCURRENCE
- SAFETY PRECAUTIONS IN PLACE
- NARRATIVE OF EVENT
- CORRECTIVE MEASURES NARRATIVE
- NOTIFICATION
- STAFF PERSON IN CHARGE OF FACILITY AT TIME OF OCCURRENCE
- WITNESS INFORMATION
- ACCUSED INFORMATION

[8] mass.gov/dph/dhcq/hcqskel.html

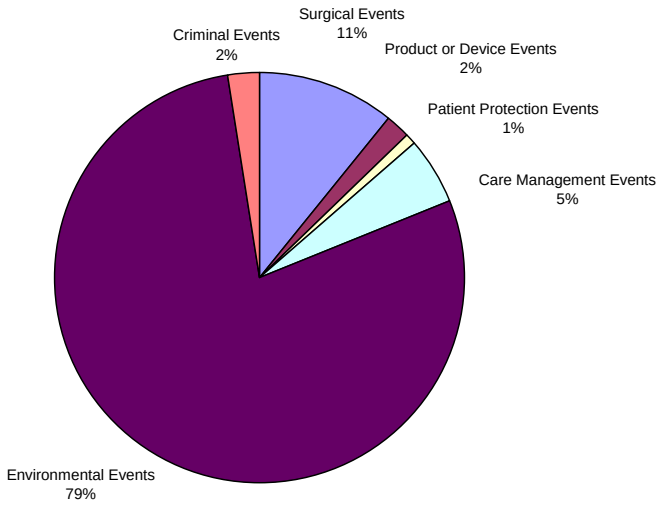
As reported in the following table, between January 1, 2008 and June 30, 2008 Massachusetts hospitals reported two hundred and five (205) serious reportable events to the Department. Falls were by far the most common event reported representing 77% of the total. Of the reported falls, six resulted in patient death and 152 resulted in serious disability as defined. The next three most common events comprised an additional 14% of the total: medication errors (5%), retained foreign objects (5%), and wrong site surgeries (4%). To date there is not enough data to support significant stratification and analysis; moreover, we caution that these gross percentages of reported events may change radically as we move forward.

Massachusetts Hospital SREs by Number and Percentage:
January 1, 2008 through June 30, 2008

Event	Count	%
Wrong Surgical Procedure	2	1%
Wrong Site Surgery	9	4%
Wrong Patient Surgery	1	0%
Transfusion Error	0	0%
Suicide/Suicide Attempt	2	1%
Stage 3 or 4 Pressure Ulcer	1	1%
Spinal Manipulation	0	0%
Sexual Assault	5	2%
Retained Foreign Object	10	5%
Restraints/Bedrails	0	0%
Physical Assault	0	0%
Oxygen or Gas Error	0	0%
Medication Error	10	5%
Maternal Death/Disability	0	0%
Infant Discharged to Wrong Person	0	0%
Impersonation of Health Professional	0	0%
Hypoglycemia	0	0%
Hyperbilirubinemia in Neonate	0	0%
Fall	158	77%
Elopement	0	0%
Electric Shock	0	0%
Device Malfunction	3	2%
Death < 24 Hours ASA 1 Patient	0	0%
Contaminated Drugs or Device	0	0%
Burn	3	2%
Artificial Insemination Error	0	0%
Air Embolism	1	1%
Abduction	0	0%
Total	205	100%

Combining the reported events into their six NQF categories yields the following distribution:

Distribution of Serious Reportable Events in Massachusetts Hospitals: January 1, 2008 - June30, 2008 (N=205)



To illustrate one way in which theses data may be useful, we have calculated an aggregate statewide SRE rate for acute care hospitals only of 8.49 events per 100,000 patient days by annualizing the SREs and by using 2006 patient days, the most current year available. In preparing this report we systematically reviewed materials provided by other states which employ the NQF SRE classification system. In the future it will be instructive to compare categorical SRE rates controlling for demographic differences and other significant characteristics. Minnesota and Indiana are the states with the most recent comparable data. However, for a variety of reasons[9], comparisons at the present time are statistically without merit, and may in fact lead to erroneous conclusions.

The 2007 release of the NQF 2006 update[10] expanded the reportable event list to 28 and extended the definition of reportable falls to include those falls resulting in serious disability in addition to those falls resulting in death. As a result, there is no available data that is completely comparable. We reviewed data from some states, e.g. New Jersey and Connecticut, which include non-fatal falls, but which have otherwise

[9] Such reasons include the limitations of the Massachusetts SRE data as discussed and the comparability of institutions reporting, e.g. Massachusetts data at this time does not include public and chronic disease or rehabilitation hospitals, nor does it currently include information from other sites of care such as dialysis centers or free-standing ambulatory surgery centers..

[10] National Quality Forum. *Serious Reportable Events in Healthcare-2006 Update.* Washington, D.C: National Quality Forum; 2007

modified their reporting and systems in incompatible ways. Other states, e.g. Minnesota and Indiana, follow the 28-category NQF classification system but have not as yet included non-fatal falls in their reported data.

In the following table we have annualized and modified the Massachusetts data by excluding the 152 non-fatal falls to make the NQF event category data comparable with the recently reported Minnesota and Indiana 2007 data. However, for the reasons discussed, these SRE comparisons are presented for illustrative purposes only, and no conclusions should be drawn. In the future, as the data itself and then separately the factors determining comparability each become more reliable, they should help in drawing our collective attention to areas that need more scrutiny.

First, as the data itself becomes more reliable, it will be of great benefit to review each category of error in the context of its demographic signature; its common location in the hospital, e.g. most falls occur in patient rooms; and for example, the status and types of procedures and protocols in place during its occurrence. Over time, the collection and dissemination of this information should help point to the specific areas of communication, training, shift change protocols and other areas critical to patient safety and health.

Second, regarding comparing findings across states, a good example of the danger inherent in comparing data collected in different jurisdictions may be found in reviewing reportable events related to medication errors. For a number of years, the Department and the Massachusetts hospital industry have made the identification and reporting of medication errors a matter of highest priority. Massachusetts hospitals reported ten instances of serious medication error during the first half of 2008, a relatively high number on a per inpatient day basis compared with figures reported by other states using NQF or NQF-modified reporting systems. Connecticut hospitals, for example, reported no medication errors in the four consecutive quarters ending mid-year 2007.[11] However, there is no credible basis for us to assume that patients are at greater or lesser risk of medication error in Connecticut than in Massachusetts; what we can do is hypothesize that Massachusetts providers are perhaps doing a better job of reporting at this time. We may also hypothesize that Massachusetts patients may well be at lesser risk of medication error due to the proactive efforts on the parts of the health care community during the past decade.

Another example of the difficulty in drawing conclusions at this time has to do with the reported incidence of Stage 3 or 4 Pressure Ulcers, severe and very dangerous bedsores. Massachusetts hospitals reported a single incident of a pressure ulcer-related SRE in the first half of 2008. Numerous other states with adverse medical error reporting systems, including Connecticut, Minnesota, Indiana and New Jersey have consistently reported much higher incidence rates. Maine's experience, however, mirrors our own. The majority of these patients are admitted to hospitals directly from long term care facilities, and one might reasonably hypothesize that the difference in reporting across states may have more to do with the differences between (and the acceptance and coding of) referring and admitting diagnoses than with the actual prevalence of stage 3 or 4 ulcers attributable to acute care facilities. Another hypothesis is that Massachusetts hospitals are simply under-reporting.

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12 www.ct.gov/gov/dph/lib/dph/governmental_relations/2007reports_-_october_2007.pdf

These hypotheses may or may not prove to be true; we simply do not have a sufficiently reliable base of information at this time to know. It is for these reasons that we caution that the following SRE rate comparison is presented for illustrative purposes only.

Multistate Comparison of SRE Rates

	MA[12]		MN[13]		IN[14]	
SRE	#	Rate*	#	Rate*	#	Rate*
Surgical Events	44	1.09	60	2.14	45	1.10
Product or Device	8	0.20	5	0.18	2	0.05
Patient Protection	4	0.10	3	0.11	2	0.05
Care Management	22	0.55	49	1.75	38	0.93
Environmental	16	0.40	4	0.14	5	0.12
Criminal	12	0.30	4	0.14	9	0.22
Total	106	2.63	125	4.46	101	2.47
***SRE count/100,000 patient days						
Patient Days	4,025497[15]		2,800,000		4,085,801	

D. CONCLUSION

It is difficult to draw meaningful conclusions about serious reportable events in Massachusetts hospitals based on only six months of data. Not only is the sample size limited, but it has been collected for the first time according to new criteria which has not reliably been interpreted consistently by all reporting organizations. Furthermore, the data are not yet easily comparable to data reported in other jurisdictions and/or in accordance with other, different reporting requirements and definitions.

As SRE reporting becomes more consistent we will be able to perform the statistical analyses that should help point us to the specific areas in communication, job training, physical safety protocols and other areas critical to creating and sustaining optimal patient care environments. We can say, however, that the data collection system itself is working, and that communication between reporting institutions and the Department continues to be excellent, which should result in more uniformity of interpretation of the

[12] Massachusetts Department of Public Health/Division of Health Care Quality, 2008

[13] www.health.state.mn.us/patientsafety/ae/aereport0108.pdf

[14] www.in.gov/isdh/files/2007_MERS_Report.pdf

[15] Massachusetts Division of Health Care Finance and Policy (DHCFQ-403/2006: adjusted to exclude non-acute licensed facilities).

reporting categories in future periods. It is hoped - and based on the first six months' performance, there is every reason to believe - that the SRE reporting process will achieve the goal inspiring its adoption: better collection and reporting of data leading to rigorous analysis, which in turn will lead to best practices and best outcomes. The interim results reported to date and summarized above will assist the Department in the further implementation of the SRE reporting requirements and most importantly in working with reporting institutions to develop processes to address the most frequent and most dangerous events as identified in the ongoing reporting and data analysis process.

In the current absence of national standards for assessing patient safety, the hope is that such data-gathering and data-sharing efforts will help lead to the development of national standards for patient safety and consensus benchmarks for individual hospital and system-wide performance measurement and improvement.